15. MANAGEMENT MEASURES

Management measures supplement principal structures, systems, and components (SSCs) (and later, items relied on for safety [IROFS]) by providing the administrative and programmatic framework for configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigation, and records management associated with principal SSCs and personnel activities relied on for safety. Management measures are implemented through a quality assurance (QA) program in accordance with 10 CFR Part 50 Appendix B. The QA program also provides additional measures for ensuring that the design, construction, and operation of principal SSCs are controlled commensurate with their importance to safety.

15.1 QUALITY ASSURANCE

Duke Cogema Stone & Webster (DCS) submitted its MOX Project Quality Assurance Plan (MPQAP) (Rev. 2) prior to the Construction Authorization Request utilizing Option A of Section 15.1 of NUREG 1718. MPQAP Revision 3, incorporating the clarifications and commitments identified in the Safety Evaluation Report issued by the NRC on October 1, 2001, was transmitted to the U.S. Nuclear Regulatory Commission (NRC) on March 26, 2002. DCS has implemented and commits to maintaining its QA Program, which is based on the applicable requirements of Parts I and II of American Society of Mechanical Engineers (ASME) NQA-1-1994, as revised by the ASME NQA-1a-1995 Addenda and NRC Regulatory Guide 1.28 (Rev. 3).

The DCS QA Program is composed of the Quality Assurance Program Policy Statement, the MPQAP, and implementing QA project procedures. The DCS QA Program is a living program that is kept current to continuously provide the QA management measures needed for the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF). The revision of the MPQAP issued for the Construction Authorization Request provides the QA management measures for quality-affecting activities for both the Base Contract (design) and Option 1 (construction). Quality-affecting activities are defined in MPQAP Section 2.1.1, "Program Basis," as "deeds, actions, processes, tasks or work which influence the achievement or verification of quality requirements and objectives for Quality Level 1 and 2 structures, systems and components (SSCs) and their associated activities." MPQAP Section 2.2, "Graded Quality Assurance," defines the DCS quality levels for the MOX Fuel Project.

The DCS MPQAP was developed to incorporate the QA requirements from the following nuclear quality standards into the implementing QA project procedures:

- 10 CFR Part 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*
- Parts I and II of ASME NQA-1-1994, *Quality Assurance Requirements for Nuclear Facility Applications*, as revised by the ASME NQA-1a-1995 Addenda
- NRC Regulatory Guide 1.28 (Rev. 3), *Quality Assurance Program Requirements (Design and Construction).*

These nuclear quality standards form the basis for the MPQAP implementing QA requirements for the design and construction of the MFFF. Sections 1 through 18 of the MPQAP describe the QA requirements for quality-affecting activities and coincide with the 18 criteria of 10 CFR Part 50, Appendix B. Each MPQAP section lists the NQA-1-1994 Basic Requirement, NQA-1a-1995 Addenda and Regulatory Guide 1.28 (Rev. 3) applicability, and the applicable supplements and appendices that DCS commits to implementing for each of the 10 CFR Part 50, Appendix B criteria. Detailed QA requirements for each criterion are then presented in their respective sections.

The requirements of the MPQAP are applied to DCS and subcontractor MFFF design and construction activities that affect principal SSCs. Principal SSCs are defined as those SSCs determined initially to be needed to protect the public, the worker, and the environment against the radiological consequences of accidents and natural phenomena. Principal SSCs are those SSCs (and human actions) that are or are expected to be IROFS during the conduct of the Integrated Safety Analysis (ISA).

Principal SSCs were determined based on a review of the applicable regulations and MELOX and La Hague experience. Classification of principal SSCs was then confirmed or changed, as necessary, by the safety assessment of the design basis. Final classification will be based on the ISA. QA requirements are applied to principal SSCs (and their associated activities) in a graded fashion based on the SSC's safety significance.

Definitions of quality levels and the methodology used for applying a graded QA approach to principal SSCs and to IROFS after completion of the ISA are provided in MPQAP Section 2.2 and are further discussed in the following (Section 15.1.6).

15.1.1 DCS Organization

The DCS organization for the Base Contract and Option 1, as related to QA, is fully described in MPQAP Section 1.0, "Organization." This section of the MPQAP summarizes the organizational structure and Base Contract and Option 1 responsibilities of the DCS management team.

15.1.2 DCS Quality Assurance Function

The MPQAP Introduction details how the DCS QA Program is implemented and maintained during the design and construction phases of the MFFF. QA planning, implementation, and documentation of proper implementation are also described in MPQAP Section 2.0, "Quality Assurance Program." QA implementing procedures are established to ensure the availability and reliability of IROFS.

The DCS QA Program is a living program that changes with each phase of the project. QA controls are established and personnel are trained prior to controls being implemented. The DCS QA Program is based on the line organization being responsible and accountable for the quality of the assigned work. The QA organization is responsible for developing, maintaining, and implementing the DCS QA Program and verifying the achievement of quality in implementing the program through audits, surveillances, assessments, and quality engineering reviews.

The QA organization reports to the Project Manager, is independent of the line organization, and meets the independence requirements of NQA-1-1994 Basic Requirement 1, "Organization." The QA organizational structure is shown in Figure 1.0-3 in MPQAP Section 1.0 for the Base Contract and Figure 1.0-4 for Option 1. QA responsibilities are further discussed in MPQAP Section 1.2.4.2, "QA Manager."

15.1.3 Provisions for Continuing Quality Assurance

The MPQAP was implemented during the early design phase of the project and will be maintained as a living document through deactivation of the MFFF. The MPQAP and applicable implementing QA project procedures are reviewed and revised as necessary to reflect any changes that occur during the design, construction, operation, and deactivation phases of the project. In addition, the MPQAP and implementing procedures are revised when corrective actions and regulatory, organizational, or work scope changes warrant changes to the DCS QA Program. The section titled "Provisions for Continuing QA" in the Introduction of the MPQAP addresses when the MPQAP will be revised and how revisions will be submitted to the NRC.

15.1.4 Management Measures

Management measures are addressed in the MPQAP Introduction. This section of the MPQAP summarizes the applicable MPQAP sections and QA requirements for each of the following management measures:

- Quality Assurance
- Configuration Management
- Maintenance
- Training and Qualification of Plant Personnel
- Procedures
- Audits and Assessments
- Incident Investigations
- Records Management.

The application of these management measures ensures that principal SSCs (before completion of the ISA) and particularly IROFS (after completion of the ISA) are available and reliable to perform their design function.

15.1.5 Regulatory Guide 1.28

DCS commits to meeting the requirements of ANSI/ASME NQA-1-1994 and ASME NQA-1a-1995 Addenda for design and construction, as well as the specific qualification criteria for inspection and test personnel, QA records, and internal and external audit requirements as mandated by Regulatory Guide 1.28 (Rev. 3). DCS's commitment to these requirements is addressed in MPQAP Section 2.0.

15.1.6 Graded Quality Assurance Process

15.1.6.1 Categorization of SSCs

MPQAP Section 2.2 discusses the process by which principal SSCs are assigned a quality level classification commensurate with the SSCs' safety significance. Initially, the safety significance of principal SSCs was established using a deterministic method based on an evaluation of applicable regulations and the MELOX and La Hague experience. Assignment of SSCs into QA classifications (i.e., quality levels) is based on the definitions found in MPQAP Section 2.2. Classification will be confirmed or revised by the ISA.

15.1.6.2 Identification of Quality Assurance Controls

MPQAP Section 2.2 addresses the application of graded controls on principal SSCs according to their safety function and significance. These controls are determined to provide a safety benefit by allowing preferential allocation of resources to more significant principal SSCs and by reducing the resources allocated to SSCs of lesser or no safety significance while maintaining reasonable confidence in SSC performance.

SSCs that are relied on for preventing or mitigating design basis events and ensuring compliance with the performance requirements of 10 CFR §70.61 are IROFS and designated QL-1. QL-1 SSCs are further categorized during detailed design commensurate with their safety significance.

SSCs whose single failure can directly result either in a criticality accident or in exceeding 10 CFR §70.61 public (i.e., offsite) radiological performance requirements are designated QL-1a. These SSCs are normally subject to all of the applicable controls of the MPQAP. No grading of QA controls applies to these SSCs unless justified on a case-by-case basis.

SSCs whose failure, in conjunction with the independent unlikely failure of an additional SSC, can result in a criticality accident or a release in excess of 10 CFR 70.61 public or worker radiological, chemical, or environmental performance requirements are designated QL-1b. These SSCs may have reduced QA controls. Justification for such grading is documented in accordance with the applicable QA procedure.

SSCs that are not IROFS and are not required to meet 10 CFR §70.61 performance requirements but that support normal operations of the facility (e.g., occupational exposure, radioactive waste management) and also function to further reduce public, worker, and environmental risks (e.g., physical interaction protection, radiological and criticality alarms) are designated Quality Level 2 (QL-2). These SSCs have selected (graded) QA controls applied to the extent they are needed consistent with their intended function. Selection and documentation of these controls is in accordance with the applicable QA project implementing procedure.

15.1.6.3 Feedback Mechanisms

MPQAP Section 2.2 addresses control of feedback mechanisms needed to ensure that changes to design; lessons learned from adverse trends; corrective actions due to nonconformances and deficiencies from audits, surveillances, and assessments; and construction activities result in

changes to graded QA controls to maintain reasonable confidence in SSC performance. Changes in QA controls are reviewed and documented in accordance with applicable QA project procedures.

15.1.6.4 Reassessing Safety Significance

MPQAP Section 2.2 addresses the reassessment of SSC safety significance and potential reclassification resulting from changes in construction activities or changes in facility design. The impact of such changes is evaluated and documented in the applicable project documents. The applicable procedures for the DCS design control process and configuration management process ensure that the impact of changes is reviewed and evaluated before implementation. Reclassification and subsequent changes in the application of QA controls are also controlled by the applicable QA procedures.

15.1.7 Quality Assurance Program Updates

DCS commits that the MPQAP and applicable implementing procedures will be revised to reflect any necessary changes that occur between the construction approval and the license application to possess and use special nuclear material (SNM). This commitment is documented in the section titled "Provisions for Continuing QA" in the MPQAP Introduction.

15.1.8 10 CFR Part 21

DCS is subject to the requirements of 10 CFR Part 21, "Reporting of Defects and Nonconformances" for design, construction , procurement, testing, and operations of all Quality Level 1 SSCs. Appropriate procedures for implementing these requirements will be described in the license application for possession and use of SNM.

MPQAP Section 4.0, "Procurement Document Control," commits to invoking the requirements of 10 CFR Part 21 on suppliers of materials, parts, components, and services that affect IROFS SSCs.

15.2 CONFIGURATION MANAGEMENT

This section describes the configuration management program for SSCs, throughout the design, construction, testing, operation, and deactivation of the MFFF. This section will be updated to include additional details of the operational configuration management program in the license application for possession and use of SNM. Configuration management of SSCs is implemented through requirements of the MPQAP and associated QA procedures.

15.2.1 Configuration Management Policy

Configuration management for SSCs is provided throughout MFFF design, construction, testing, operation, and deactivation. Configuration management provides the means to establish and maintain consistency among design requirements, the physical configuration, and facility documentation. During design and construction, the Engineering Manager has responsibility for configuration through the design control process. Design documentation is controlled under the configuration management requirements in accordance with the DCS MPQAP and appropriate

QA procedures associated with configuration management, design control, document control, records management, and other interfacing processes. Design changes to SSCs undergo a formal change and review process, including interdisciplinary reviews as appropriate, in accordance with these procedures.

Configuration management provides the means to establish and maintain the essential features of the design basis of SSCs. Elements of the configuration management program ensure that changes to the facility's design and design bases are appropriately connected to physical implementation of those changes within the facility, and in turn provide for continued safe operation of the facility. As the MFFF project progresses from design and construction to operation, configuration management is maintained by the engineering organization as the overall focus of activities changes.

During the design phase of the project, configuration management is based on the design control provisions of Section 3 of the MPQAP and associated procedural controls over design documents to establish and maintain the technical baseline. Design documents that provide design input, design analysis, or design results are identified with the appropriate quality level (i.e., commensurate with that of the associated SSCs). During the construction phase of the project, changes to design documentation issued for construction, procurement, or fabrication are systematically reviewed and verified, evaluated for impact, and approved prior to implementation (also in accordance with MPQAP and procedural requirements). Proper implementation is verified and reflected in the design basis documentation.

During licensed operation, changes to the MFFF will be reviewed and processed in accordance with the requirements of 10 CFR §70.72, reflected in QA and operating procedures, prior to implementation as described in Section 5.7.3.

15.2.1.1 Scope of Structures, Systems, and Components

The scope of SSCs under configuration management includes all SSCs and provides reasonable assurance that the safety functions of principal SSCs (and IROFS, following confirmation through the Integrated Safety Analysis) are properly controlled, and that changes to principal or non-principal SSCs do not inadvertently create an unanalyzed condition. Design documents subject to configuration management include calculations, safety analyses, design criteria, engineering drawings, system descriptions, technical documents, and specifications that establish design requirements. During the design phase, these design documents and considered under configuration management when approved.

The scope of documents included in the configuration management program expand throughout the design process as the project transitions to construction and operation.

During construction, start-up, and operation, the scope of documents under configuration management expands to include, as appropriate: vendor data; test data; inspection data; startup, test, operating and administrative procedures, and nonconformance reports. These documents include supporting documentation and are generated through functional interfaces with QA, maintenance, and training and qualifications of personnel. The configuration management

program provides for evaluation, implementation, and tracking of changes to SSCs, processes, equipment, computer programs and activities of personnel.

15.2.1.2 Interfaces with Other Management Measures

The configuration management program is implemented through or otherwise related to other management measures. Key interfaces and relationships to other management measures are described below:

- **Quality Assurance** – The MPQAP is described in Section 15.1. The QA program established the framework for configuration management and other management measures.

- **Records** – Records are generated and processed in accordance with applicable requirements of the MPQAP and provide evidence of the conduct of activities associated with configuration management.

- **Maintenance** – Maintenance is described in Section 15.3. Maintenance requirements are established as part of the design basis which is controlled under configuration management. Maintenance records provide evidence of compliance with preventative and corrective maintenance schedules.

- **Training and Qualifications** – Training and qualification is controlled in accordance with the applicable provisions of the MPQAP as described in Section 15.4. Personnel qualifications and/or training to specific processes and procedures are management measures that support the safe operation, maintenance, or testing of principal SSCs. Training and qualification requirements and documentation of training may be considered part of the design basis controlled under configuration management.

- **Corrective Action** – Audits, assessments, and incident investigations are described in Sections 15.6 and 15.7. Corrective actions identified as a result of these management measures may result in changes to design features, administrative controls, or other provisions of the configuration management program through the MPQAP and QA procedures. Periodic assessments of the configuration management program, described in Section 15.2.5, are also conducted in accordance with the audit and assessment program described in Section 15.6.

- **Plant Procedures** – Operating, administrative, maintenance, and emergency procedures are discussed in Section 15.5. These procedures are used to conduct various operations associated with principal SSCs and will be reviewed for potential impacts to the design basis.

15.2.1.3 Objectives of Configuration Management

The objective of configuration management is to ensure design and operation within the design basis of Principal SSCs by: identifying and controlling preparation and review of documentation associated; controlling changes; and maintaining the physical configuration of the facility consistent with the approved design.

Configuration control is accomplished during design through the use of procedures for controlling design, including preparation, review (including interdisciplinary review), and design verification where appropriate, approval, and release and distribution for use. Engineering documents are marked with a quality level classification (e.g., documents associated with IROFS are QL-1) and receive reviews and verifications, consistent with their safety significance, prior to being issued. Changes to the approved design also are subject to a change and review process to ensure consistency with the design bases of principal SSCs.

Configuration verification is also accomplished through design verification, which ensure that design documents are consistent and that design requirements for principal SSCs are met. During construction and testing, this verification also extends to verification that as-built configurations are consistent with the design, and that testing that is specified to demonstrate performance of principal SSCs is accomplished successfully. Periodic audits and assessments of the configuration management program and other design reviews confirm that the program meets its goals and that the design is consistent with the design bases. Incident investigations are conducted in accordance with the MPQAP and associated procedures in the event problems are encountered. Prompt corrective actions are developed as a result of incident investigations or in response to adverse audit/assessment results, in accordance with QA procedures.

These goals are accomplished during operation with similar activities associated with changes to the facility in accordance with 10 CFR § 70.72 and with periodic audits and assessments of the configuration management program and the physical facility, including walkdowns as appropriate.

15.2.1.4 Description of Configuration Management Activities

Configuration management includes those activities conducted under the design control provisions of MPQAP Section 3 for ensuring that design and construction documentation is prepared, reviewed, and approved in accordance with a systematic process. This process includes interdisciplinary reviews appropriate to ensure consistency between the design and the design bases of principal SSCs. During construction, it also includes those activities that ensure that construction is consistent with those design documents. Finally, it includes activities that provide for operation in accordance with the limits and constraints established in the ISA, and that provide for control of changes to the facility in accordance with 10 CFR §70.72. These activities are discussed in the section above and in the MPQAP.

Configuration management includes designation of principal SSCs under the QA classification and grading provisions of Section 2 of the MPQAP. The graded approach to controlling SSCs includes applying the most stringent QA controls to SSCs with the highest safety significance. The less stringent controls applied to principal SSCs with less safety significance as nonetheless controlled under configuration management and the applicable controls are documents in the same way as other principal SSCs. QA classification (i.e., quality levels) and grading are accomplished in accordance with QA procedures.

Configuration management also includes records to demonstrate that personnel conducting activities that are relied on for safety or that are associated with principal SSCs are appropriately qualified and trained to conduct that work.

Implementing documents are controlled within the document control system discussed in Section 6 of the MPQAP. These documents support configuration management by ensuring that only reviewed and approved operating, test, calibration, surveillance, and maintenance procedures and specifications and drawings are used for procurement, construction, installation, testing, operation, and maintenance of SSCs, as appropriate. Maintenance, including post-maintenance testing, and plant procedures for the operating facility are discussed in Sections 15.3 and 15.5, respectively.

Configuration management is supported by document control and records management in accordance with Sections 6 and 17, respectively, of the MPQAP, which are implemented in part through an electronic data management system (EDMS). Additional databases may include trending of deficiencies and corrective actions, which are controlled in accordance with the appropriate audit, assessment, and incident investigation procedures. Additional databases may be used as part of the operating facility and will be controlled in accordance with appropriate software control procedures, including verification and validation as applicable.

Startup testing is also subject to configuration management. Additional details of MFFF startup testing and any operational readiness reviews conducted as a result of the conclusions of the ISA will be discussed in the license application for possession and use of SNM.

15.2.1.5 Organization Structure and Staffing Interfaces

During design and construction, the configuration management program is administered by the MFFF Engineering organization. MFFF Engineering (described in Chapter 4) includes engineering disciplines with responsible lead engineers in charge of each discipline, under the direction of design managers who report to the Engineering Manager. The lead discipline engineers have primary technical responsibility for the work performed by their disciplines, and are responsible for the conduct of interdisciplinary reviews as discussed previously in this section. Reviews are also conducted, as appropriate, by construction management, operations, QA, regulatory/ISA, and procurement personnel. The design control process also interfaces with the document control and records management process via QA procedures.

During licensed operation, the configuration management program is expected to be administered by the operations organization, with the regulatory management organization providing review and assessment functions consistent with radiological and criticality safety functions and audit/assessment functions. The QA organization will continue to maintain QA program audit and assessment responsibilities. Additional information regarding the operations-phase configuration management program will be provided in the license application for possession and use of SNM.

15.2.2 Design Requirements

Design requirements and associated design bases are established and maintained by the MFFF Engineering organization. The configuration management controls on design requirements and the safety assessment of the design bases are described previously in this section. Design requirements are documented in a design requirements document which provides for a hierarchical distribution of these requirements through basis of design documents. The design requirements document and basis of design documents are controlled under the design control provisions of the configuration management system as described above, and are subject to the same change control as analyses, specifications, and drawings. Computer codes used in the design of principal SSCs are also subject to design control measures, with additional requirements as appropriate for software control, verification, and validation.

Principal SSCs are designated as QL-1 (IROFS) and associated design documents are subject to interdisciplinary reviews and design verification as appropriate. Analyses constituting the safety assessment of the design bases, and later the ISA, are subject to the same requirements. Changes to the design are evaluated to ensure consistency with the design bases. Methods for conducting the safety assessment of the design bases of principal SSCs are described in Chapter 5.

The design bases documented in Chapters 5 through 11 are consistent with those flowed down from and/or described in the design requirements document, basis of design documents, and the analyses, specifications, and drawings constituting the preliminary design, including the analyses supporting the safety assessment. The configuration management system captures these requirements and resulting design bases in accordance with design control, document control, and records management procedures. The MFFF Engineering organization maintains the configuration management program using QA procedures and document control and records management processes and procedures.

15.2.3 Document Control

Document control is implemented for the MFFF in accordance with Section 6 of the MPQAP and associated QA procedures. The EDMS is used both to file project records and to make available the latest revision (i.e., the controlled copy) of design documents. The EDMS provides an "official" copy of current analysis, specification, technical report, drawing, or procedure, and DCS personnel are trained to use this system to retrieve controlled documents. The system is capable of generating indices of controlled documents, which are uniquely numbered (including revision number). Controlled documents are maintained until cancelled or superseded, and cancelled or superseded documents are maintained as a record, currently for the life of the project or termination of the license, whichever occurs later. Section 15.8 discusses records management. Hard-copy distribution of controlled documents is provided when needed in accordance with applicable QA procedures (e.g., when EDMS access is not accessible).

As part of the configuration management system, the document control system captures the following documents, either through controlled documents (as appropriate) or records generated by the associated QA procedures:

- Design requirements, through the controlled copy of the design requirements document

- The design bases, through the controlled copy of the basis of design documents
- The safety assessment of the design bases of principal SSCs, through the controlled copies of supporting analyses
- QA procedures
- Training records
- Engineering documents including analyses, specifications, technical reports, and drawings; and documentation generated by management measures such as audits and assessments.

15.2.4 Change Control

QA procedures control changes to the technical baseline. The process includes an appropriate level of technical, management, and safety review and approval prior to implementation. During the design phase of the project, the primary method of controlling changes is the design control process described in Section 3 of the MPQAP and associated QA procedures. This process includes the conduct of interdisciplinary reviews which constitute a primary mechanism for ensuring consistency of the design with the design bases. During both construction and operation, appropriate reviews to ensure consistency with the approved safety assessment of the design bases of principal SSCs and the ISA, respectively, will similarly ensure that the design is constructed and operated/modified within the limits of the design basis. Additional details are provided below.

15.2.4.1 Design Phase

Changes to the design include a systematic review of the design bases for consistency. In the event of changes to reflect design or operational changes from the established design bases, both the safety assessment and other documents affected by design bases of SSCs – including the design requirements document and basis of design documents, as applicable – are properly modified, reviewed, and approved prior to implementation. Approved changes are made available to personnel through the document control function discussed previously in this section.

During design, the primary method of ensuring consistency between documents, including consistency between design changes and the safety assessment, is the interdisciplinary review process. The Licensing and Safety Analysis Manager leads the safety assessment function, and performs interdisciplinary reviews as appropriate to ensure design changes either (1) do not impact the safety assessment, (2) are accounted for in subsequent changes to the safety assessment or ISA, or (3) are not approved or implemented.

15.2.4.2 Construction Phase

When the project enters the construction phase, changes to documents issued for construction, fabrication, and procurement will be documented, reviewed (including interdisciplinary reviews as appropriate), approved, and posted against each affected design document. Vendor drawings and data also undergo an interdisciplinary review, as appropriate, to ensure compliance with

procurement specifications and drawings, and to incorporate interface requirements into DCS documents as appropriate.

Upon NRC authorization of construction, design changes will be evaluated against the approved design bases of principal SSCs. Numerous changes are expected to the design as detailed design progresses and construction begins. A systematic process consistent with the process described above will be employed to evaluate changes in the design against the design bases of principal SSCs and/or the ISA (as a function of the state of development of the ISA). DCS will notify the NRC of potential changes that reduce the level of commitments or margin of safety in the design bases of principal SSCs, and will not implement such changes without prior NRC approval.

15.2.4.3 Operations Phase

During licensed operation, changes to design will also be documented, reviewed (including interdisciplinary reviews as appropriate), and approved prior to implementation.

Upon receipt of the license to possess and use SNM, DCS will implement a change process that fully implements the provisions of 10 CFR §70.72. This process will be described in more detail in the license application for possession and use of SNM.

15.2.5 Assessments

Periodic assessments of the configuration management program are conducted to determine the program's effectiveness and to correct deficiencies. These assessments will include review of the adequacy of documentation and the as-built facility (as appropriate during construction and operation). Such audits and assessments will be conducted and documented in accordance with QA procedures and the overall facility audit and assessment program described in Section 15.6.

15.3 MAINTENANCE

This section outlines the maintenance program to be implemented for the operations phase of the MFFF. The maintenance program will be described in more detail in the license application for possession and use of SNM. Preventive maintenance activities, surveillance, and performance trending provide reasonable and continuing assurance that IROFS will be available and reliable to perform their safety functions.

The purpose of planned and scheduled maintenance for IROFS is to ensure that the equipment and controls are kept in a condition of readiness to perform the planned and designed functions when required. Appropriate plant management is responsible for ensuring the operational readiness of IROFS under this control. For this reason, the maintenance function is administratively closely coupled to operations. The maintenance function plans, schedules, tracks, and maintains records for maintenance activities.

DCS commits to implementation of a maintenance program as described below for the MFFF.

15.3.1 Safety Controls

Maintenance requirements for IROFS (e.g., calibration frequency, functional testing requirements, and replacement of specified components) will be specified to ensure the reliability/availability of IROFS commensurate with the risks identified in the ISA.

15.3.2 Maintenance Elements

Maintenance activities generally fall into the following categories:

- Surveillance/monitoring
- Preventive maintenance
- Corrective maintenance
- Functional testing.

These maintenance categories are discussed in the following sections.

15.3.2.1 Surveillance/Monitoring

Surveillance of IROFS, including instrument calibration and testing, is performed at specified intervals. The purpose of the surveillance program is to measure the degree to which IROFS meet performance specifications. The results of surveillances are trended, and when the trend indicates potential IROFS performance degradation, preventive maintenance frequencies are adjusted or other appropriate corrective action is taken.

Incident investigations may uncover root causes of failures that are related to the type or frequency of maintenance. The lessons learned from such investigations are factored into the surveillance and preventive maintenance programs as appropriate.

Maintenance procedures prescribe compensatory measures, if appropriate, for surveillance tests of IROFS that can be performed only while equipment is out of service.

15.3.2.2 Preventive Maintenance

Preventive maintenance includes preplanned and scheduled periodic refurbishment, partial or complete overhaul, or replacement of IROFS, if necessary, to ensure their continued safety function. Planning for preventive maintenance includes consideration of results of surveillance and monitoring, and includes instrument calibration and testing.

15.3.2.3 Corrective Maintenance

Corrective maintenance involves repair or replacement of equipment that has unexpectedly degraded or failed. Corrective maintenance of IROFS restores the equipment to acceptable performance through a planned, systematic, controlled, and documented approach for the repair and replacement activities.

15.3.2.4 Functional Testing

Functional testing of IROFS is performed as appropriate following initial installation, as part of periodic surveillance testing, and after corrective or preventive maintenance or calibration to ensure that the item is capable of performing its safety function when required. Functional testing is conducted using approved procedures that include compensatory measures, if appropriate, while the test is being conducted.

15.3.3 Work Control Methods

Maintenance-related work control methods include maintenance management and tracking (i.e., integration of maintenance activities with ongoing operations activities), interfaces with radiation protection and associated work permits, implementation of lockout/tagout requirements, and maintenance procedures for IROFS.

15.3.4 Relationship of Maintenance Elements to Other Management Measures

The maintenance function interfaces with the configuration management system by obtaining the approved and controlled drawings, specifications, and procedures for the item to be maintained. Through the training program, personnel are trained in the maintenance of IROFS. Procedures are used for maintenance of IROFS. Records of performance trends and maintenance history for IROFS are maintained in the maintenance management system.

15.4 TRAINING AND QUALIFICATIONS OF PLANT PERSONNEL

This section describes the training program for the operations phase of the MFFF. The training program requirements apply to those plant personnel who perform activities relied on for safety. The MPQAP provides training and qualification requirements, during the design and construction phases, for QA training of personnel performing quality-affecting activities; for nondestructive examination, inspection, and test personnel; and for auditors.

DCS commits to the establishment of an operational training program in accordance with the description below. This information will be updated as appropriate with the license application for possession and use of SNM.

15.4.1 Organization and Management of Training

Line managers are responsible for the content and effective conduct of training for their personnel. Training responsibilities for line managers are included in position descriptions, and line managers are given the authority to implement training for their personnel. The training organization provides support to line managers by facilitating the planning, directing, analyzing, developing, conducting, evaluating, and controlling of a systematic performance-based training process, which may include a graded approach, that fulfills job-related training needs.

Plant procedures establish the requirements for indoctrination and training of personnel performing activities relied on for safety. Exceptions from training requirements may be granted when justified and documented in accordance with procedures and approved by appropriate management.

Lesson plans are used for classroom and on-the-job training to provide consistent subject matter. When design changes or plant modifications are implemented, updates of applicable lesson plans are included in the change control process of the configuration management system.

Auditable training records are maintained to support management information needs associated with personnel training, job performance, and qualifications.

15.4.2 Analysis and Identification of Functional Areas Requiring Training

A needs/job analysis is performed and tasks are identified to ensure that appropriate training is provided to personnel.

The training organization consults with relevant technical experts as necessary to develop a list of tasks for which personnel training for specific jobs is appropriate. The list of tasks selected for training is reviewed and compared to the training materials as part of the systematic evaluation of training effectiveness. The task list is also updated as necessitated by changes in procedures, processes, plant systems, equipment, or job scope.

15.4.3 Position Training Requirements

Minimum training requirements are developed for those positions whose activities are relied on for safety. Initial identification of job-specific training requirements is based on experience from MELOX and La Hague and United States facility experience. Entry-level criteria (e.g., education, technical background, and/or experience) for these positions are contained in position descriptions.

15.4.4 Basis for and Objectives of Training

Learning objectives identify the training content, as established by needs/job analyses and position-specific requirements. The task list from the needs/job analysis is used to develop action statements that describe the desired post-training performance. Objectives include the knowledge, skills, and abilities the trainee should demonstrate; the conditions under which required actions will take place; and the standards of performance the trainee should achieve upon completion of the training activity.

15.4.5 Organization of Instruction

Lesson plans are developed from the learning objectives which are based on job performance requirements. Lesson plans and other training guides are developed under the guidance of the training function. Lesson plans are reviewed by the training function and, generally, by the organization cognizant of the subject matter. Lesson plans are approved prior to issue or use. Lesson plans are used for classroom training and on-the-job training as required.

15.4.6 Evaluation of Trainee Learning

Trainee mastery of learning objectives is evaluated through observation/demonstration or oral or written tests as appropriate. Such evaluations measure the trainee's skills and knowledge of job performance requirements.

15.4.7 Conduct of On-the-Job Training

In addition to appropriate classroom training, on-the-job training is used for IROFS activities when appropriate. On-the-job training is conducted using current performance-based training materials by designated personnel who are competent in the program standards and methods of conducting the training. Completion of on-the-job training is demonstrated by actual task performance where feasible and appropriate. When the trainee cannot perform the actual task, a simulation of the task is performed with the trainee explaining task actions using the conditions encountered during the performance of the task, including references, tools, and equipment reflecting the actual task to the extent practical.

15.4.8 Systematic Evaluation of Training Effectiveness

Under the direction of the training function, the training program is systematically evaluated periodically to measure the program's effectiveness in producing competent employees. Feedback is provided by the trainees after completion of classroom training sessions to provide data for this evaluation for program improvements. These evaluations identify program strengths and weaknesses, determine whether the program content matches current job needs, and determine if corrective actions are needed to improve the program's effectiveness. The training function is responsible for leading the training program evaluations and for implementing any corrective actions. Program evaluations may consist of an overall periodic evaluation or a series of topical evaluations over a given period.

Evaluation objectives that are applicable to the training program or topical area being reviewed are developed and may address the following elements of training:

- Management and administration of training and qualification programs
- Development and qualification of the training staff
- Position training requirements
- Determination of training program content, including its facility change control interface with the configuration management system
- Design and development of training programs, including lesson plans
- Conduct of training
- Trainee examinations and evaluations
- Training program assessments and evaluations.

Evaluation results are documented, and noteworthy practices and weaknesses are highlighted in the training program. Identified deficiencies are reviewed, improvements are recommended, and changes are made to procedures, practices, or training materials as necessary.

15.4.9 Personnel Qualification

The qualification requirements for key management positions are given in Chapter 4. While Chapter 4 currently stresses the organization for the design and construction of the MFFF, it will

be revised with the license application for possession and use of SNM to address operations and the qualifications of key plant management positions.

The qualification requirements for technical personnel are determined as discussed in Section 15.4.2. Training and qualification requirements associated with quality-affecting activities are given in the MPQAP. Such requirements include QA training for project personnel and qualification of nondestructive examination personnel, inspection and test personnel, personnel performing special processes, and auditors.

15.4.10 Provisions for Continuing Assurance

Personnel performing activities relied on for safety are evaluated at least biennially to determine whether they continue to understand, recognize the importance of, and have the qualifications to perform their activities that are relied on for safety. The evaluation may be by written test, oral test, or on-the-job performance evaluation. The results of the evaluation are documented. When the results of the evaluation dictate, retraining or other appropriate action is provided. Retraining is also required due to plant modifications, procedure changes, and QA program changes that result in new or changed information that needs to be disseminated.

15.5 PLANT PROCEDURES

This section outlines the provisions for plant procedures to be implemented for the startup, testing, and operations phases of the MFFF. The MPQAP provides requirements during the design and construction phases for QA procedures, which detail the controls for design input, processes, verification, changes, and approval. Plant procedures will be described in more detail in the license application for possession and use of SNM.

15.5.1 Types of Procedures

Generally, four types of plant procedures are used to control activities: operating procedures, administrative procedures, maintenance procedures, and emergency procedures.

Operating procedures are used to directly control process operations. These are procedures for workstation and control room operators. Operating procedures include directions for normal operations, including startup and some testing, operation, and shutdown, as well as off-normal conditions of operation, including alarm response. Operating procedures include required actions to ensure radiological and nuclear criticality safety, chemical safety, fire protection, emergency planning, and environmental protection. They include operating limits and controls and specific direction regarding administrative controls to ensure operational safety. If needed, safety checkpoints (e.g., hold points for radiological or criticality safety checks, QA verifications, or operator independent verification) are identified at appropriate steps in the procedure.

Administrative procedures are used to perform activities that support the process operations, including management control activities such as the following:

- Configuration management
- Nuclear criticality, radiation, chemical, and fire safety

- Human-system interface
- Quality assurance
- Design control
- Plant personnel training and qualification
- Audits and assessments
- Incident investigations
- Record keeping and document control
- Reporting.

Maintenance procedures address preventive and corrective maintenance, surveillance (i.e., calibration, inspection, and other surveillance testing), and functional testing following maintenance. Where appropriate, maintenance procedures include requirements for pre-maintenance activity involving reviews of the work to be performed and reviews of procedures.

Emergency procedures address the preplanned actions of operators and other plant personnel in the event of an emergency.

15.5.2 Preparation of Procedures

DCS will identify necessary plant procedures on the basis of past operating experience and review of the design including the ISA. Plant procedures are prepared by individuals assigned by management. Procedures are approved by cognizant management. The MPQAP contains requirements for design control of IROFS, including design inputs, processes, outputs, changes, interfaces, and records.

Operating and maintenance procedures are prepared by individuals knowledgeable of the applicable process operations and are reviewed by cognizant management. Where appropriate, operating procedures are validated through a field test or dry run prior to initial use.

15.5.3 Use of Procedures

Plant procedures govern the conduct of operations involving IROFS and management control systems supporting those IROFS. Activities involving licensed SNM are conducted in accordance with approved procedures. Compliance with procedures is enforced, and operators are trained to report inadequate procedures and/or the inability to follow procedures.

Procedures either are available at work locations or are readily accessible where needed to perform work. Procedures specify that operations personnel must be notified prior to and following maintenance on IROFS.

15.5.4 Management Control of Procedures

Following approval, plant procedures are issued for use and entered into the configuration management system. The training program ensures that necessary personnel are trained in the use of the approved procedures. Change control for plant procedures is the same as for other items in the configuration management system. Procedures are modified, as appropriate, in

conjunction with plant or process modifications. Plant procedures are reviewed at least every five years to ensure their continued accuracy and usefulness. Emergency procedures are reviewed annually for the first two years of plant operation and biennially thereafter. If procedural inadequacy is identified as a root cause from an incident investigation, applicable procedures are reviewed and modified as necessary.

Provisions for temporary changes to plant procedures will be addressed in the license application for possession and use of SNM.

15.5.5 Preoperational Testing Program

DCS will develop a preoperational testing program for the MFFF. During the latter part of startup, depleted uranium and plutonium oxides will be used to test systems to the extent feasible.

Procedures for test control will be developed for the preoperational testing program. The procedures will provide criteria for determining when a test is required or how and when testing activities are performed. Tests will be performed under conditions that simulate, to the extent feasible, the most adverse design conditions as determined by analysis. Test results will be documented and evaluated, and their acceptability will be determined by a responsible individual or group.

Operating, administrative, maintenance, and emergency procedures will be developed during startup prior to the introduction of depleted uranium and plutonium oxides. Procedures will be validated during startup testing of the MFFF.

15.6 AUDITS AND ASSESSMENTS

15.6.1 General

15.6.1.1 Graded Approach to Audits and Assessments

DCS audits and assessments are performed in accordance with the DCS MPQAP requirements for SSCs and associated activities commensurate with their safety significance. Audits are addressed in MPQAP Section 18.0, "Audits," and assessments are addressed in MPQAP Section 2.4, "Management Assessments." The quality level is used to establish the frequency and rigor by which principal SSCs/IROFS are audited and assessed. MPQAP audit/assessment requirements focus primarily on principal SSCs/IROFS. Principal SSCs/IROFS receive the most oversight in the form of audits and assessments. Other SSCs and their associated activities are also audited and assessed but to a lessor rigor and frequency than IROFS, as determined by DCS management.

Audits and assessments provide DCS management feedback both on the technical adequacy of SSCs and activities by evaluating how well the DCS QA Program is being implemented and on QA program effectiveness in ensuring that SSCs are properly designed and constructed in accordance with applicable QA requirements.

15.6.1.2 Scheduling of Audits and Assessments

Audits/assessments of principal SSCs/IROFS are scheduled in a manner to provide coverage, consistency, and coordination with ongoing work and at a frequency commensurate with the project status and importance of the work. Functional areas performing work controlled by the MPQAP are audited at least once a year.

Results from audits, assessments, surveillances, deficiencies, and corrective action reports are used to determine the scope and frequency by which each functional area is subsequently audited. Audits are scheduled to begin as early in the life of the work as practical and scheduled to continue at intervals consistent with the schedule for accomplishing the work. As specified by NRC Regulatory Guide 1.28 (Rev. 3), *Quality Assurance Program Requirements (Design and Construction)*, external audits of principal SSC/IROFS suppliers are performed prior to contract placement, and these suppliers are evaluated annually and fully audited every three years after initial placement on the DCS Approved Suppliers List.

Annually, the DCS Project Manager conducts a project assessment to determine the overall effectiveness of the DCS QA Program. Annually, each functional area performing work on principal SSCs/IROFS also performs an internal management assessment of its activities. Additional audits and assessments of specific functions (as directed by management to provide an adequate assessment of compliance and effectiveness) supplement regularly scheduled internal audits and assessments.

15.6.1.3 Procedures for Audits and Assessments

Internal and external audits and assessments are conducted using DCS-approved procedures that meet the MPQAP requirements for these activities. These procedures provide requirements for the following audit/assessment activities:

- Scheduling and planning of the audit/assessment
- Certification requirements of audit/assessment personnel
- Development of audit plans and audit/assessment/surveillance checklists
- Performance of the audit/assessment
- Reporting and tracking of findings to closure
- Closure of the audit/assessment.

The applicable project procedures emphasize timely reporting and correction of findings to prevent recurrence.

15.6.1.4 Qualifications and Responsibilities of the QA Manager and QA Verification Manager

The DCS QA Manager has overall responsibility for managing the DCS QA Program, including QA audits and assessments of quality-affecting activities. Reporting to this position is the QA Verification Manager, who is directly responsible for ensuring that QA internal and external audits and QA internal management assessments are conducted in accordance with the requirements of the MPQAP. The QA Verification Manager is responsible for the following:

- Establishing and implementing the Lead Auditor/Auditor Certification Program
- Managing the programs for internal/external audits, surveillance, supplier survey, and evaluation
- Promptly reporting findings to management
- Evaluating the effectiveness of implementation of the DCS QA Program
- Approving audit plans and audit/assessment/surveillance checklists
- Approving audit/assessment/surveillance reports
- Maintaining the DCS Approved Suppliers List
- Providing input for continuous program improvements.

The roles and responsibilities of the DCS QA Manager and the QA Verification Manager established at the start of the design phase will carry over into the construction and operations phases of the project. Both the DCS QA Manager and the QA Verification Manager have the education, formal training, and previous experience necessary to manage their assigned areas. This experience includes previous audit/assessment/surveillance management experience under the controls of an audit program.

15.6.1.5 Training, Qualifications, and Responsibilities of Audit/Assessment Personnel

Auditors, lead auditors, and assessment personnel are responsible for performing audits and assessments in accordance with the applicable QA procedures. Auditors and lead auditors hold certifications as required by the MPQAP to perform audits. Before being certified under the DCS QA Program, auditors and lead auditors must complete training on the following under the direct supervision of a lead auditor:

- DCS QA Program
- Audit fundamentals, including audit scheduling, planning, performance, reporting, and followup action involved in conducting audits
- Objectives and techniques of performing audits
- On-the-job training.

Certification of auditors and lead auditors is based on the QA Verification Manager's evaluation of education, experience, professional qualifications, leadership, sound judgment, maturity, analytical ability, tenacity, and past performance and completion of QA training courses. A lead auditor must also have participated in a minimum of five QA audits or equivalent verifications within a period of time not to exceed three years prior to the date of certification. Equivalent verifications include management assessments, pre-award evaluations or comprehensive surveillances (provided the prospective lead auditor took part in the planning, checklist development, performance, and reporting of the verification activities). One audit must be a nuclear-related QA audit or equivalent verification within the year prior to certification. Certification meets the requirements of Supplement 2S-3, "Supplementary Requirements for the

Qualification of Quality Assurance Program Audit Personnel," as required by ASME NQA-1-1994.

Personnel performing assessments are not required to be certified, but they are required to complete QA orientation training, as well as training on the management assessment project procedure.

Administration of audit and assessment training is addressed in MPQAP Section 15.4, "Training and Qualification of Plant Personnel."

15.6.1.6 Authority and Access of Audit/Assessment Personnel

The MPQAP and implementing audit and assessment procedures require that assigned auditors and assessment personnel be independent of any direct responsibility for performing the work being audited or assessed. Audit personnel have management-directed authority and organizational freedom to make the audit process meaningful and effective, including making recommendations for program improvements. DCS management directs line managers to grant the teams access to relevant information and personnel in order to properly audit or assess the assigned areas or activities.

15.6.1.7 Determination of Acceptable Performance

Procedures and audit/assessment checklists establish applicable acceptance criteria from which audit/assessment team members determine acceptable performance of principal SSCs/ IROFS. The QA Verification Manager concurs with the audit/assessment team determinations upon reviewing the QA internal/external audit and internal QA management assessment reports. Internal management assessment results and acceptance of performance results for each functional area are approved by the respective functional area manager who directs the performance of the assessment. The DCS Project Manager approves the results of the project management assessment, thereby concurring with performance acceptance determinations.

15.6.1.8 Use of Audit/Assessment Procedures and Checklists

Applicable project procedures detail the audit and assessment processes. These procedures establish the implementing steps required to be performed. Audit and assessment checklists identify the specific requirements to be verified during the audits/assessments.

The QA Verification Manager approves the checklists for internal/external audits and internal management assessments. The functional area managers approve the checklists used for the internal management assessments, and the DCS Project Manager approves the checklist for the project management assessment. The applicable project procedures and checklists, however, do not prohibit the audit/assessment teams from pursuing additional areas during the course of the audits/assessments, especially those areas discovered during the audit/assessment that appear not to meet established requirements.

15.6.1.9 Conduct of Audits and Assessments

Audits and assessments are conducted by:

- Using the approved audit/assessment checklist
- Interviewing responsible personnel
- Performing plant area walkdowns (which may include out-of-the-way or limited-access areas)
- Reviewing controlling plans and procedures
- Observing work in progress
- Reviewing completed QA documentation as applicable.

The nature of the principal SSCs/IROFS dictates what combination of these tools is used to evaluate the effectiveness of the item or activity being audited or assessed. The audit/assessment team leader determines the appropriate techniques. If findings result, the deficiencies are documented in sufficient detail to provide for accurate evaluation and timely corrective actions.

15.6.1.10 Immediate Correction of Audit/Assessment Deficiencies

Audit and assessment procedures allow for immediate correction of deficiencies found during the audit/assessment. If the deficiency appears to be an isolated event, typographical error, and/or easy to correct, line management may correct the deficiency in accordance with the applicable project procedures. In this case, the audit/assessment checklist and report reflect that the deficiency was corrected and provide documentation of the controlling procedure for the correction. Although no further action is required as a result of the identified corrected deficiency, the fact that it occurred is documented by the DCS QA organization for tracking and trending deficiencies. Corrected deficiencies, along with other identified deficiencies, are periodically evaluated for potential trends that may warrant further corrective actions to prevent recurrence.

15.6.1.11 Management Review

Management responsible for the areas being audited or assessed are briefed by the audit/assessment team leader on the results of the audit/assessment, including any deficiencies identified that require corrective action. Notification of any deficiencies allows management to investigate the deficiencies and to plan for corrective actions prior to the issuance of the formal audit/assessment report but will not inhibit prompt and complete documentation and reporting.

15.6.1.12 Audit/Assessment Reports and Timely Correction

The audit/assessment team leader is required to develop the audit/assessment report documenting the audit/assessment findings, observations, and recommendations for program improvement. These reports provide DCS management with documented verification of project performance against established performance indicators for principal SSCs/IROFS. These reports are developed, reviewed, approved, and issued following established formats and protocols detailed in the applicable project procedures. Responsible managers are required to review the reports and provide any required responses due to reported deficiencies.

Corrective actions following issuance of the audit/assessment report require compliance with the applicable project procedure for corrective actions as implemented in accordance with the requirements of MPQAP Section 16, "Corrective Action." Deficiencies are required to be evaluated and corrected in a timely manner. Audit and assessment reports are also required to contain an effectiveness evaluation and statement for each of the applicable QA program elements reviewed during the audit/assessment. The DCS QA organization verifies completion of corrective actions, and the audit/assessment is closed with the proper documentation as required by the applicable audit and assessment procedure.

15.6.1.13 Quality Trend Analysis and Deficiency Followup

Audit/assessment results are tracked by the DCS QA organization. These data are periodically analyzed for potential trends and needed program improvements to prevent recurrence and/or for continuous program improvements. The resulting trend is evaluated and reported to applicable DCS management. This report documents the effectiveness of management measures in controlling project activities, as well as deficiencies. Deficiencies identified in the trend report require corrective action in accordance with the applicable procedure. The DCS QA organization also performs followup reviews on identified deficiencies and verifies completion of corrective actions reported as a result of the trend analysis. Verification of completion of corrective actions is documented in accordance with the applicable project procedure for corrective actions.

15.6.2 Audits

15.6.2.1 Audit Teams

Personnel assigned to audit teams are independent of the areas and activities being audited. Audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective. Audit teams are led by a DCS-certified lead auditor. The lead auditor is appointed by the QA Verification Manager to supervise the team, organize and direct the audit, prepare and coordinate issuance of the audit report, and evaluate responses. Audit team members may come from the line organization to assist in assessing the adequacy of technical processes. These "borrowed" team members are required to be independent of the assigned areas for the audit. They receive training in the audit procedure and QA orientation training, and they are certified by the QA Verification Manager as technical specialists in the areas needed for the assigned audit scope based on their individual areas of expertise.

15.6.2.2 Conduct and Reporting of Audits

The DCS QA organization audits and evaluates internal DCS MOX Fuel Project activities that are controlled by the MPQAP using applicable procedures. These audits cover both programmatic and technical requirements through compliance- and performance-based audit plans and checklists. External suppliers of items and services are evaluated using the applicable supplier evaluation project procedure.

Internal and external audit findings are reported to responsible DCS and/or supplier management at the exit interview and in the final audit/supplier evaluation report so that appropriate corrective actions may be initiated in a timely manner. The QA Verification Manager establishes response

dates in the audit report for the planned corrective actions. Followup reviews of evidence of completion of needed corrective actions are also performed to close out the audits and supplier evaluations.

Findings resulting from audits or supplier evaluations are closely tracked to completion. Routinely, DCS management receives a status report of open findings. This report is generated to keep management informed of the progress of the corrective actions and to provide management the opportunity to expedite completion of planned corrective actions.

Internal audits of DCS activities under the controls of the DCS MPQAP will change in regard to audit checklist attributes and the method of implementation as the project progresses through the construction, testing, operations/maintenance, and deactivation phases. Audit attributes shift from a compliance-based audit approach to a combination compliance- and performance-based audit approach as the MFFF enters the construction and operations phases of the project.

During construction, audits check as-built conditions against controlled drawings, installation specifications, and procedures based on committed construction codes and standards. During operations, audits verify that operating prerequisites are met, plant operations are within approved parameters, required surveillance testing is performed, approved acceptance criteria are met, and operating procedures are properly followed and their completion is documented in accordance with the DCS QA Program.

15.6.3 Assessments

15.6.3.1 Project and Management Assessments

The Project Manager conducts a project management assessment annually to determine if the DCS QA Program is effective on a corporatewide basis. The Project Manager appoints a team of DCS managers and/or supervisors/employees or uses outside contractors to conduct this assessment. The individual areas covered by each project assessment team member are assessed by individuals who have received training in the appropriate procedures and who have no direct responsibility for the items/areas being assessed. Functional area managers and the QA Manager also conduct an internal management assessment annually of QA activities under their control. Personnel assigned to do the internal management assessments are also trained in the appropriate procedures and do not have supervisory or management responsibility for the areas being assessed. The managers report the results of the internal management assessments to the Project Manager for review. The results of both the project and internal management assessments are reviewed by senior management to determine the adequacy of implementation of the DCS QA Program and to direct any needed changes for program improvements.

15.6.4 DCS Provisions for Continuing Assurance

The DCS QA Program is maintained current through deactivation of the MFFF. Audit and assessment procedures and the MPQAP are kept current as the project progresses, and appropriate changes are made based on any of the following:

- Lessons learned from audit/assessment findings

- Program improvements identified from analysis of trends
- Changes due to regulations, commitments, reorganizations, revised project schedule, or program improvements from continuous review of oversight results and process improvement initiatives.

The DCS audit and assessment procedures and resulting program will be updated to reflect any necessary changes that occur between the DCS MFFF construction approval and the license application for possession and use of SNM. Any necessary changes to audit/assessment programs are reviewed and approved in accordance with the DCS procedure for controlling the MPQAP and its implementing project procedures.

15.7 INCIDENT INVESTIGATIONS

15.7.1 Incident Investigation and Corrective Action Process

The DCS incident investigation and deficiencies/corrective action process in use during the design and construction phases of the MFFF is described in MPQAP Section 16, "Corrective Action," and is implemented by the applicable procedures. The process for design, construction, and operations includes management controls to:

- Promptly identify incidents/findings
- Evaluate the need to stop work
- Assign an independent individual or teams to investigate incidents/findings
- Evaluate the significance of the incident/finding
- Evaluate the root cause for significant incidents/findings
- Plan needed corrective actions
- Obtain management approval of planned actions
- Implement acceptable corrective actions
- Complete planned corrective actions
- Verify completion of corrective actions
- Track and evaluate incidents/findings for adverse trends.

Corrective/deficiency action reports and incident investigation reports are maintained as QA records. These records are used for evaluating lessons learned, periodically evaluating potential trends, and determining additional QA program improvements to prevent recurrence.

15.7.2 Corrective Action Process Administration

The DCS Incident Investigation and Deficiencies Corrective Action Process is administered by the DCS QA organization during the design and construction phases of the MFFF. This process will be modified prior to startup testing to include the additional specific actions that are needed to support an operating facility. In addition, results from the corrective action process will be compared against the ISA to ensure it adequate reflects or bounds real incidents. Changes to the facility will be controlled under the configuration management program.

The license application for possession and use of SNM will contain a detailed description of this process for operations. The resulting program will address the prompt investigation of incidents that:

- Makes use of appropriately qualified investigative teams, as necessary, to evaluate operational incidents, determine root causes and generic implications (commensurate with the severity of the incident) using systematic procedures, and recommend corrective actions in a timely manner
- Provides for monitoring and documenting of corrective actions (including effectiveness) through completion, including tracking/trending as appropriate of results to facilitate improvements to future operations
- Describes the plan and methodology for investigating incidents, including identification of roles and responsibilities and scope of authority of investigation teams
- Ensures investigators are appropriate independent and appropriately qualified in the applicable processes and in root cause analysis, as appropriate
- Establishes appropriate documentation and records requirements.

15.8 RECORDS MANAGEMENT

15.8.1 Records Management Program Description

DCS has implemented a records management program for controlling records management responsibilities and the generation, review, approval, classification, verification, indexing, storage, protection, maintenance, correction, retrieval, and disposition of QA records as described in the MPQAP. The DCS Records Management Program complies with Basic Requirement 17 and Supplement 17S-1 of NQA-1-1994 Part I as revised by Regulatory Guide 1.28 (Rev. 3). The DCS Records Management Program consists of the following:

- Applicable project procedures
- Dual-facility records storage using an electronic data management system (EDMS) and storage of backup tapes in a fireproof safe
- Use of fireproof filing cabinets or vault protection for documents that cannot be placed in the EDMS due to size, content, or record media (e.g., radiographs, pictures, microfilm, and magnetic media).

Classified records are maintained separately from QA records and in accordance with procedures that satisfy the requirements of the DCS Security Plan.

The DCS Records Management Program was established during the design phase of the MFFF with ample flexibility to be used during the construction and operations phases as well. As the project progresses into each phase, the records management system will be modified to include the necessary electronic "folders" to properly store and retrieve records. Records that become contaminated during facility operation are handled in accordance with DCS procedures. The following records will also be stored in this system:

- Records controlled under the DCS configuration management system for the design, construction, and operation of the MFFF
- Training records
- Dosimetry, effluent, operations, and maintenance records.

15.8.2 Record Generation

DCS project procedures control the content, generation, review, and approval of DCS records. Once verified as complete by the originating organization, records are transmitted to DCS records management.

15.8.3 Receipt of Records

Records personnel review the transmitted documents for completeness, legibility, correct file storage designation, and suitability for scanning. If acceptable, the record copy is entered into the electronic systems and then checked against the transmitted hard copy. Records personnel also issue the document under a controlled distribution, as required, to those individuals identified by the document owner/originator as needing a controlled copy.

15.8.4 Record Storage, Preservation, and Safekeeping

Acceptable documents are placed in the electronic records location identified by the generator. The records are also linked to interfacing records when applicable. DCS has elected to retain all documents submitted under the controls of the DCS QA Program for the lifetime of the project (i.e., through deactivation and termination of the license), thereby classifying all DCS QA records as "lifetime records."

Records personnel maintain authorizations for placing records into and accessing records from the records systems. Stored files are "read only" files to protect the records against tampering, theft, or loss. Records are routinely backed up, and the backup is stored in a fireproof safe. Access controls also prevent unauthorized access.

Records personnel also control hard-copy storage of records that cannot be stored electronically. These hard-copy records are stored in access-controlled fire-proof cabinets. Computer codes and computerized data used for IROFS are stored in the electronic systems with documentation of the version of code used for the specific data.

15.8.5 Record Correction

Records requiring correction or revision are retrieved by authorized individuals as established in the applicable procedures for generating the record. Corrections of records are limited to minor changes (e.g., editorial changes) in accordance with the appropriate procedure. When revision is required, the change requires creation of a new document with the next assigned revision number. The original record is retained, and the revision is processed in accordance with the applicable project procedures. Once approved, this new record is transmitted to records management.

15.8.6 Record Retrieval

DCS establishes file locations (or folders) needed for its scope of work. These file folders, plus interfacing links to associated documents/records, are structured to ensure timely retrievability of needed records.

15.8.7 Disposition of Records

All "lifetime" records are stored for the operating life of the MFFF. If DCS reclassifies any "lifetime" QA records to "nonpermanent" record status, the following conditions are required to be met in accordance with the MPQAP and the records management project procedures:

- Verification that the record was retained for a minimum of three years
- Verification that associated regulatory requirements are met
- Verification that the MFFF status allows document disposal
- Verification that associated MPQAP requirements are met
- Written concurrence from the DCS QA Manager allowing record disposal.

15.8.8 Records Management Program Changes

The DCS QA organization routinely performs audits, surveillances, and assessments of document control and records management functions to evaluate the implementation of the DCS QA Program. Such oversight may produce findings and observations, which could result in changes to the DCS Records Management Program. DCS monitors document control and records management activities for program improvements. Any changes to the program are administered through revisions to the applicable procedure. Procedure revisions are reviewed and approved in accordance with the applicable procedure.

15.8.9 DCS Provisions for Continuing Records Management

The DCS Records Management Program procedures are kept current for the duration of the project. Revisions to the records management procedures can result from any of the following:

- Lessons learned during implementation
- Corrective actions due to internal and external audits, surveillances, and assessments
- Needed program improvements due to analysis of trends
- Changes due to regulations, commitments, reorganizations, revised project schedule, or program improvements from process improvement initiatives.

The DCS Records Management Program will also be updated to reflect any needed changes that occur between the DCS MFFF construction approval and the license application for possession and use of SNM.

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